K073508

510(K) SUMMARY

Substantially equivalent

SEP 1 1 2008

General Information

Applicant's Name and Address:	OCULUS Optikgeräte GmbH Münchholzhäuser Straße 29 D-35582 Wetzlar
Date of Summary:	18 August 2008
Owner/Operator Number:	8010318
Contact person:	Mr. Joerg Iwanczuk Product Manager

Device Name

Trade Name:	PARK 1
Class:	Class II
Classification Name:	Scheimpflug Camera
Product Code:	MXK Anterior Eye-Segment Analysis System
Regulation Number:	886.1850

Predicate Devices

The PARK 1 is claimed to be substantially equivalent to the following currently market device:

Pachycam, Scheimpflug Camera, OCULUS Optikgeraete GmbH, Germany; K 041841

Auto-Ref-Keratometer, CANON Inc.; exempted (21CFR886.1760)

Device Description:

The PARK 1 is a non-invasive, diagnostic system created to:

- take photos of the anterior segment of the eye
- measure the refractive power of the eye
- measure the central corneal K-values.

The device is stationary and AC powered. The PARK 1:

- is based on the Scheimpflug Principle for Slit Image photography. The measuring system uses blue light (UV-free) given to a slit to illuminate the eye, and a CCD-Camera for photography. The device takes a series of images of the anterior segment of the eye from one fixed location (180°) and analyses one, selected by software
- has a real keratometer to measure directly the central keratometer values as per definition in the 3.1mm ring.
- includes an Ophthalmic Refractometer to measure the refractive power of the eye (21CFR886.1760)

The device consists of a measurement unit, built in CPU, head and chin rest and an external power supply.

Product Comparison between PARK 1 and Pachycam

	OCULUS Pachycam	**New device, PARK 1**
Manufacturer	OCULUS Optikgeräte GmbH	OCULUS Optikgeräte GmbH
Measuring Principle	Scheimpflug Principle for Slit Image photography	Scheimpflug Principle for Slit Image photography
Observation Illumination	Infrared LED 800nm for pupil illumination	Infrared LED 950nm for pupil illumination
Flash Output Illumination	Blue LED Light (UV-free) 455nm, max. 2.5W Power Input	Blue LED Light (UV-free) 460nm, max. 2.5W Power Input
Camera	CCD-Camera	CCD-Camera
Display	Data digital, displayed on a CPU	Data digital, displayed on a CPU
Image resolution	640 x 480 pixel	640 x 480 pixel
Measuring points	600 per image	600 per image
Image size	4.8mm x 3.6mm	4.8mm x 3.6mm
Photographic range	Fixed slit position in 180°	Fixed slit position in 180°
Photographic Series	5 images	5 images
Exposure Control	Fixed during calibration, max 2.5Wsec. Power input	Fixed during calibration, max 2.5Wsec. Power input
Slit Length	5mm fixed	5mm fixed
Illumination time during alignment	Limited to 300 seconds	Limited to 300 seconds
Where used	Hospital, ambulance	Hospital, ambulance
Intended use	Please refer to the detailed description	
Sterilisation	Not necessary	Not necessary
Materials	Housing is made of Polyurethane, specially treated, not inflammable	Housing is made of Polyurethane, specially treated, not inflammable
Mechanical safety	Please refer to the detailed description	
Power supply	External, 110/220 VAC,	External, 110/220 VAC,

	50/60Hz	50/60Hz
Power Consumption	27 VA	49,5 VA
Power requirement	9 VDC, 3A	15VDC, 3,3A see test certificate
Weight	1 kg	12 kg

Basics for Substantial Equivalence

The PARK 1 utilizes same or similar operating systems.

In comparison to the device Pachycam, Oculus Optikgeräte GmbH, it contains:

- same Scheimpflug optical system,
- same source of illumination for observation and photography,
- same CCD-Camera as photographic medium,
- same Keratometer for the central corneal keratometer readings
- same alignment system

In comparison to the Ophthalmic Refractometer, Canon Inc, exempted (21CFR886.1760), it contains

- same measurement principle

The PARK 1 has same intended use:

In comparison to PACHYCAM:

to photograph the eye and take Scheimpflug images of the anterior segment of the eye to evaluate the thickness of the cornea. The implanted keratometer measures the central radii of the cornea.

In comparison to the Ophthalmic Refractometer:

to measure the refractive power of the eye (21CFR886.1760).

The PARK 1 and the Pachycam uses same device features like a

- head stabilizing device
- external fixation target
- joy stick for control mechanism.

The PARK 1 and the Pachycam are considered "Non Invasive" as defined in 21 CFR §812.3(k) and considered not to be a "Significant Risk Device" as defined in 21 CFR §812.3(m).

Indications for Use

Intended Use:

The PARK 1 is designed to photograph the eye and take Scheimpflug images of the anterior segment to evaluate the thickness of the cornea. The implanted keratometer measures the central radii of the cornea. The implanted Ophthalmic Refractometer measures the refractive power of the eye (21CFR886.1760)

Safety

The PARK 1 is a non-invasive diagnostic system, which contacts the patient only on his/her chin and forehead. The PARK 1 does not present or pose any new or additional effects for risk on the safety prescribed intended uses. The light output is of an eye safe intensity and wavelength. The electrical safety requirements for medical devices are met. The PARK 1 is proven effective for its intended uses through internal company studies.

Brief summary of nonclinical tests and results

In an internally performed study 46 subjects (92 eyes) were examined with an OCULUS PARK 1 by the same operator to determine the repeatability of the measurement results of the Pachymetry and Keratometry. Both eyes of a patient were measured and every eye was measured three times with the same device. The measurement ranges of the examined eyes were: Apical Thickness [460 .. 636µm]; Min. Thickness [453 .. 635µm] ; K1 [38.66 .. 46.04dpt] ; K2 [39.02 .. 47.14dpt].
For this study design repeatability is a pooled standard deviation across subjects and eyes calculated in the following manner: For each set of triplicate results per eye per subject, the variance (standard deviation squared) had been calculated. Then these variances were averaged and the square root of the average had been taken.

Measurement	**Value**	**Repeatability**	**SD[1]**	
			Min.	**Max.**
Pachymetry	Apical Thickness	4.79 µm	0.00 µm	14.74 µm
	Min. Thickness	5.51 µm	0.58 µm	14.93 µm
Keratometry	K1	0.11 dpt	0.00 dpt	0.35 dpt
	K2	0.12 dpt	0.00 dpt	0.31 dpt

[1] : SD : Standard Deviation (across triplicate results)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1 2008

Oculus Optikgeräte GmbH
c/o Joerg Iwanczuk
Product Manager
OCULUS Optikgeräte GmbH
Muenchholzhaeuser Strasse 29
Wetzlar D-35582
Germany

Re: K073508
Trade Name: PARKONE
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: MXK, HLQ, HKO
Dated: May 13, 2008
Received: June 30, 2008

Dear Mr. Iwanczuk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K073508
Device Name: PARK 1

Indications For Use:

The PARK 1 is designed to photograph the eye and take Scheimpflug images of the anterior segment to evaluate the thickness of the cornea. The implanted keratometer measures the central radii of the cornea. The implanted Ophthalmic Refractometer measures the refractive power of the eye.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K073508